

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robyn WARD et al.  
Title: ASSESSMENT OF DISEASE RISK BY QUANTITATIVE  
DETERMINATION OF EPIMUTATION IN NORMAL TISSUES  
Int'l. Appl. No.: PCT/AU2004/001434  
Int'l. Filing Date: 10/20/2004  
Examiner: Unassigned  
Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR §1.56

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

The documents being cited in the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding international application. A copy of the International Search Report is attached setting forth the portion of the documents considered relevant by the examiner. A copy of the cited references listed in the Search Report are not being submitted herewith.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 20 April 2006

By S. A. Bent

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

Stephen A. Bent  
Attorney for Applicant  
Registration No. 29,768

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: April 20, 2006

(use as many sheets as necessary)

Sheet

1

of

1

## Complete if Known

Application Number	Unassigned	10/576575
Filing Date	April 20, 2006	
First Named Inventor	Robyn Lynne WARD	
Group Art Unit	Unassigned	1634
Examiner Name	Unassigned	Amanda Shaw
Attorney Docket Number	037775-0107	

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	A1		WO 2000/026401 A		5/11/2000		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A2	C.R. HOLST et al., "Methylation of p16 <sup>INK4</sup> a promoters occurs in vivo in histologically normal human mammary epithelia", Cancer Research 63, 1596-1601, April 2003.	
	A3	H. NAKAYAMA et al., "Molecular detection of p16 promoter methylation in the serum of colorectal cancer patients", Cancer Letters, 188, pp. 113-119, 2002.	
	A4	S.A. KUISMANEN et al., "Genetic and epigenetic modification of MLH1 accounts for a major share of microsatellite-unstable colorectal cancers", American Journal of Pathology 156(15) (2000), pp. 1773-1779.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.S./

Examiner  
Signature

/Amanda Shaw/

Date  
Considered

03/09/2010

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.